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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,618	04/04/2000	Hartwig Josef B. Wehrmann	P04357USO PHI 1246	6214

27310 7590 07/26/2002

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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/542,618

Applicant(s)

WEHRMANN ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-19 and 21-32 is/are rejected.
- 7) ☒ Claim(s) 1-4 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This Office action is in response to the Remarks filed 15 May 2002.
2. Applicant's statement regarding the deposit of biological material on page 3 of the Remarks is noted. The ATCC Accession Number must be filled in where appropriate to clearly provide the identifying characteristics of Applicant's maize hybrid line designated 39J26. Compliance with this requirement may be held in abeyance since Applicant's specification provides evidence that the deposit has been or will be made. Applicant must provide the appropriate amendment to insert the deposit information at the time of allowance in both the specification and the claims. Applicant's attention is directed to the changes regarding deposit of biological materials, the time period for making a biological deposit, and an amendment to add the depository information to the specification, after a Notice of Allowability is no longer extendible. See 37 CFR § 1.136(c) and 1.809(c), revised in [Changes to the Time Period for Making any Necessary Deposit of Biological Material](#), 66 Fed. Reg. 21090 (April 27, 2001), 1246 Off. Gaz. Pat. Office 104 (May 22, 2001), [effective for Notices of Allowability mailed on or after May 29, 2001](#).¹ Amendments are no longer permitted to be filed after the payment of the issue fee. See 37 CFR § 1.312, revised in [Changes to Application Examination and Provisional Application Practice](#), 65 Fed. Reg. 14865, 14869 and 14873 (March 20, 2000), 1233 Off. Gaz. Pat. Office 47, 50 and 54 (April 11, 2000), effective on May 29, 2000.

¹ The Official Gazette published on May 22, 2001 has the wrong effective date.

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3. The rejection of claim 1, 5 and 7 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn in view of Applicant's statement concerning deposit of hybrid maize line 39J26 as discussed above.

4. The rejection of claim 11, 15, 19, 24, 28 and 32 under 35 U.S.C. § 112, second paragraph, as directed to the phrase "said maize plant" in said claims is withdrawn by the Examiner in view of Applicant's arguments (page 4 of the Remarks). Applicant should note that the instant claims have been rejected under 35 U.S.C. § 112, second paragraph, in this Office action for other issues related to the indefiniteness of said claims, as outlined below.

5. The rejection of claims 16-19 under 35. U.S.C. § 112, first paragraph, for enablement is withdrawn in view of Applicant's arguments on pages 5-8 of the Remarks. Applicant should note that the instant claims have been rejected under 35 U.S.C. § 112, first paragraph, in this Office action for other issues related to written description and enablement related to written description of said claims as outlined below.

Claim Objections

6. Claims 1-4, 5, 7 and 20 are objected to because of the following informalities:

Claims 1, 5 and 7 are objected to because said claims would be allowable except that the ATCC Accession Number has been left blank. This objection will be maintained until such time as all of the claims are allowable. In addition, the specification is objected to at pages 7 and 36, because there is no indication of the ATCC Accession Number of deposited hybrid maize line 39J26, or the parental lines of said hybrid.

Claims 2-4 and 20 are objected to because they would be allowable except for the above issue regarding the deposit accession number.

At claim 20, line 1, the phrase "all the morphological" should read -- all of the morphological --.

7. Claims 6, 12, 16, 25 and 29 are objected to because of the following informalities:

At claim 6, the phrase "A tissue culture" should read -- The tissue culture -- in referring to claim 5.

At claims 12, 16, 25 and 29, the phrase "A hybrid maize plant" should read -- The hybrid maize plant --.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 5-11, 13-15, 17-19, 21-24, 26-28 and 30-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 5, the phrase "tissue regenerates" lacks a proper antecedent basis in the claim, which is directed to a "tissue culture of regenerable cells". It is suggested that the phrase be amended to read -- cells of a hybrid maize plant 39J26 --.

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At claims 5, 7, 11, 15, 19, 24, 28 and 32, the phrase "capable of expressing" is indefinite and does not state a positive feature of the regenerated plants, the phrase should read -- that expresses -- or -- expresses --.

At claim 6, line 1, the phrase "the cells or protoplasts being from a tissue" is indefinite because it is unclear what the metes and bounds of "being from" are. In addition, the term "protoplasts" lacks a proper antecedent basis in the claim. It is suggested that the phrase read -- the cells or protoplasts of said cells having been isolated from a tissue --.

Claim 8 is indefinite because the plant of claim 2 is not male sterile. Amending said claim to replace "is male sterile" with -- further comprises a genetic factor conferring male sterility -- would obviate this rejection. *See also claim 21.*

Claims 9, 13, 17, 22, 26 and 30 are indefinite because the claims do not set forth any positive method steps leading to the maize plant at line 1 of the claims. Hence, it is unclear what the metes and bounds of the claimed methods are. Merely "obtaining" the maize plant does not state all of the essential method steps leading to the maize plant at line of the instant claims. See MPEP § 2172.01.

Claims 10, 14, 18, 23, 27 and 31 are indefinite because they are drawn to a "maize plant breeding program" while the claims to which they depend are drawn to a method. Appropriate correction is required.

Claims 11, 15, 19, 24, 28 and 32 are indefinite because the phrases "excellent silage yield potential" "excellent grain yield potential" "excellent seedling vigor" and

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"excellent starch content of the whole plant", for example, are relative and do not state the metes and bounds of the claimed invention.

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 11, 12, 15, 16, 19, 24, 25, 28, 29 and 32 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under current written description guidelines. The claims are drawn to maize progeny plants and transgenic maize plants having undisclosed identifying characteristics whereby only the characteristics of the deposited maize line 39J26 are known. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation. In addition, at claims 12, 16, 19, 25, 28, 29 and 32, the effect of transgenes and/or single gene conversion produced by backcrossing on the physiological and morphological characteristic of a transgenic 39J26 maize plant or progeny thereof, is not sufficiently described whereby one of skill in the art could recognize the claimed maize plant. The breeding techniques encompass recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism

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enhanced selection, genetic marker enhanced selection and transformation and combinations thereof. Each of these breeding techniques would result in a structurally and phenotypically different maize plant. Over an undetermined number of generations, the identifying characteristics of each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification. While claims 11, 15, 19, 24, 28 and 32 set forth at least two 39J26 traits, because the terms used to describe the traits are relative terms, lacking a comparative basis (see 112, second paragraph rejection above), these traits do not adequately define or distinguish 39J26 progeny maize plants. Furthermore, neither the individual traits themselves, nor their degree of expression, appear to be unique to the deposited maize line 39J26. Accordingly, there is a lack of adequate description of the claimed progeny maize plants. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Hence, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday 5, 2001/ Notices; p. 1099-1111).

12. Claims 13, 14, 17, 18, 26, 27, 30 and 31 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because Applicant has failed to adequately describe the maize plants at claims 12, 16, 25 and 29, the methods for

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producing a maize plant of the instant claims are not enabled. One skilled in the art would not know how to use a plant that has not been adequately described in a method of producing a maize plant, regardless of the technique used.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

14. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 11, 15, 19, 24, 28 and 32 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Weber (U.S. Patent 6,018,113, filed 29 October 1998).

Weber discloses hybrid maize line designated 38W36 (see claim 1), which Weber discloses as capable of conferring “excellent silage yield potential” and “exceptional grain yield potential” on progeny thereof (see claim 9). Applicant should also note that because the limitations set forth in the claims lack a comparative basis as

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set forth in the 112 second paragraph rejection above, these limitations are interpreted by the Office to be identical to those taught by Weber in the instant reference. While the hybrid maize line of Weber is designated 38W36 and the parent maize variety of the instant claims is designated 39J26, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art.

Weber does not specifically disclose a method of producing maize plants using 39J26 as a parent in an unspecified number of crosses with unspecified second parents.

The maize plant of claims 11, 19, 24 and 32 would have been *prima facie* obvious to one of ordinary skill in the art at the time of applicant's invention because, depending upon what second maize plant one of skill in the art had selected and how many crosses were made, the resulting progeny could be genetically, morphologically and physiologically indistinguishable from that of a maize plant having the 38W36 maize plant of Weber as an ancestor. The maize plants of claims 15 and 28 would have been *prima facie* obvious to one of ordinary skill in the art, because depending what other maize plant was crossed with the transgenic maize plant of the instant invention or the hybrid of Weber, the resulting progeny is only required to be capable of expressing a combination of at least two traits, of which the maize plant of Weber comprises in order to read on the instant claims. Given that one of ordinary skill in the art could cross the hybrid maize plant of Weber said plant being transgenic (see claim 8) or with another, transgenic maize plant to produce a maize plant that is capable of expressing a combination of at least two traits, one of ordinary skill in the art would not have been

able to distinguish a maize plant having the hybrid of Weber as an ancestor from that of the instant invention as an ancestor. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Conclusion

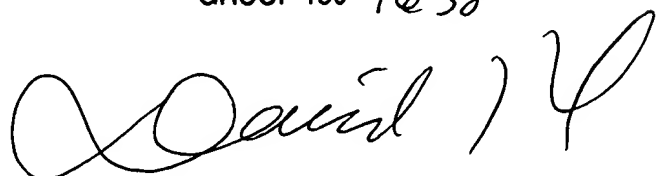
16. Claims 1-4 and 20 are objected to for the issues discussed supra.
17. Claims 5-19 and 21-32 are rejected.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

David H. Kruse, Ph.D.
23 July 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in cursive script, appearing to read "David T. Fox", followed by a large, stylized flourish or mark.